

DEC - 5 2011

K113350



GE Healthcare
510(k) Premarket Notification Submission

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: November 9, 2011

Submitter: GE Healthcare GE Healthcare, GE Medical Systems Israel,
Functional Imaging
4 HAYOZMA St
TIRAT HACARMEL, 30200, ISRAEL

Primary Contact Person: Eli Werner
Regulatory Affairs Leader

GE Healthcare GE Healthcare, GE Medical Systems Israel,
Functional Imaging
(972) 4-8563666
(972) 4-8577664

Secondary Contact Person: John Jaeckle
Regulatory Affairs Manager, MI&CT
GE Healthcare,
262-424-9547

Device: Trade Name: Brivo NM 615

Common/Usual Name: Single Photon Emission Computed Tomography (SPECT)

Classification Names: 21CFR 829.1200

Product Code: KPS

Predicate Device(s): Discovery NM 630 , K111445

Device Description: The BrivoNM615 is an all-purpose single detector nuclear imaging system intended for general nuclear medicine imaging procedures for detection of radioisotope tracer uptake in the patient body, using a variety of scanning modes supported by various acquisition types and imaging features designed to enhance image quality. The main components of the Brivo NM 615 system are: NM Gantry with Single detector head, patient table, Remote Control Unit and NM operation console. The Brivo NM 615 is a modification of its predicate device Discovery NM 630 using only single head detector instead of Dual Head detector like in the Discovery NM 630



GE Healthcare
510(k) Premarket Notification Submission

Intended Use:

The Brivo NM 615 is an emission computed tomography system intended to detect the location and distribution of gamma ray photon emitting radionuclides in the body and to produce cross-sectional images through computer reconstruction of the data. The Brivo NM 615 system is intended for General Nuclear Medicine imaging procedures using variety of scanning modes supported by various acquisition types. This generic type of device may include signal analysis and display equipment, patient and equipment supports, and accessories.

Indications for Use:

The GE Brivo NM 615 system is a medical tool intended for use by appropriately trained healthcare professionals to aid in detecting, localizing, diagnosing of diseases and in assessment of organ function for the evaluation of diseases, trauma, abnormalities, and disorders such as, but not limited to, cardiovascular disease, neurological disorders and cancer. The system output can also be used by the physician for staging and restaging of tumors, planning, guiding, and monitoring therapy.

The GE Brivo NM 615 system is a Nuclear Medicine (NM) system, which is intended to yield General Nuclear Medicine imaging procedures for detection of radioisotope tracer uptake in the patient body, using a variety of scanning modes supported by various acquisition types and imaging features designed to enhance image quality. The scanning modes include planar mode (Static, Multi-gated, Dynamic and Whole body scanning) and tomographic mode (SPECT, Gated SPECT, Whole body SPECT). The acquisition types include single and multi-isotope/multi peak frame/list mode single-photon imaging. The imaging-enhancement features include assortment of collimators, gating by physiological signals, and real-time automatic body contouring.

The GE Brivo NM 615 system may include signal analysis and display equipment, patient and equipment supports, components and accessories. The system may be used for patients of all ages.



GE Healthcare
510(k) Premarket Notification Submission

Technology: The Brivo NM 615 employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The Brivo NM615 and its applications comply with voluntary standards as detailed in Section 9, of this premarket submission. The modifications from the predicate Discovery NM 630 system were completed in accordance with GE's quality management system design controls. Engineering testing and standards compliance testing were successfully conducted and did not raise any new safety questions or identify any new risks. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

Summary of Clinical Tests:

The subject of this premarket submission, Brivo NM 615, did not require clinical studies to support substantial equivalence.

Conclusion:

GE Healthcare considers the Brivo Nm 615 to be as safe, as effective, and performance is substantially equivalent to the predicate device Discovery NM 630 (K111445).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Mr. Eli Werner
Regulatory Affairs Leader
GE Healthcare
GE Medical Systems Israel, Functional Imaging
4 Hayozma Street
30200 TIRAT HACARMEL
ISRAEL

DEC - 5 2011

Re: K113350

Trade/Device Name: Brivo NM 615
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS & JAK
Dated: November 9, 2011
Received: November 14, 2011

Dear Mr. Werner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,



Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure



GE Healthcare
510(k) Premarket Notification Submission

Indications for Use Form

510(k) Number (if known): K113350

Device Name: Brivo NM 615

Indications for Use:

The GE Brivo NM 615 system is a medical tool intended for use by appropriately trained healthcare professionals to aid in detecting, localizing, diagnosing of diseases and in assessment of organ function for the evaluation of diseases, trauma, abnormalities, and disorders such as, but not limited to, cardiovascular disease, neurological disorders and cancer. The system output can also be used by the physician for staging and restaging of tumors, planning, guiding, and monitoring therapy.

The GE Brivo NM 615 system is a Nuclear Medicine (NM) system, which is intended to yield General Nuclear Medicine imaging procedures for detection of radioisotope tracer uptake in the patient body, using a variety of scanning modes supported by various acquisition types and imaging features designed to enhance image quality. The scanning modes include planar mode (Static, Multi-gated, Dynamic and Whole body scanning) and tomographic mode (SPECT, Gated SPECT, Whole body SPECT). The acquisition types include single and multi-isotope/multi peak frame/list mode single-photon imaging. The imaging-enhancement features include assortment of collimators, gating by physiological signals, and real-time automatic body contouring.

The GE Brivo NM 615 system may include signal analysis and display equipment, patient and equipment supports, components and accessories. The system may be used for patients of all ages.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)


Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K113350